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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/911,824	08/15/1997	JOHN R. HACKETT, JR.	6165.US.01	4028

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

08/911,824

Applicant(s)

HACKETT, JR. ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 November 2002 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . 6) ☐ Other: _____ .

DETAILED ACTION

The examiner acknowledges the communication of 11/14/2002.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/14/2002 has been entered and considered.

Claims 1 and 2 are pending.

The declarations have been fully considered and are discussed below in the new rejection under 35 USC 102(a).

REJECTIONS WITHDRAWN

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention because the term "consisting essentially of" was used and it is defined very broadly in the specification.

The amended claim 1 renders the rejection moot because "open" language is now used.

Claim Rejections - 35 USC § 103

The rejection of claims 1 and 2 are withdrawn because of the amendment; however, a new rejection is made in light of this amendment, see below.

REJECTIONS MAINTAINED

Claim Objections

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Applicant has amended claim 2 to replace "comprising" with "having" and asserts that it renders the objection moot. The argument has been fully considered and not found persuasive.

Claim 2 recites "[a]n isolated HIV-1 Group O env polypeptide having an amino acid sequence having an immunoreactive portion of a polypeptide of claim 1."

"Having" was noted by the court to be open language in *Univ. of California v. Eli Lilly*, 43 USPQ2d 1398 (CA FC 1997). The use of "having" in the claims opens the

claims up to include unrecited elements even in large amounts consistent with the recitation of "comprising". The claim has the same meaning as before amendment.

The claim is drawn to any HIV-1 Group O *env* polypeptide which shares any one immunogenic portion of SEQ ID NO:61. It therefore encompasses Group O *env* proteins which share a single immunoreactive portion with SEQ ID NO:61. Claim 2 includes proteins that are outside the scope of claim 1, since the extent of variation of Group O *env* proteins can go beyond those that have the limitations recited in claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the full scope of the claimed invention.

Claim 1 is drawn to Group O *env* proteins which are 80% identical to SEQ ID NO:61. The claim encompasses Group O *env* proteins that have not yet been discovered, and the specification provides no basis to predict the structural and functional characteristics of the as-yet undiscovered Group O *env* proteins. Claim 2 is

even more broadly drawn, to any Group O env protein which shares any one immunoreactive portion with any of the claim 1 proteins. Therefore, the claims are drawn to a genus of proteins, and the specification only describes one species within the genus. The specification does not reasonably convey possession of the full gamut of Group O env proteins claimed, from the description of one species within the genus.

Applicant argues that the claims have been amended, that polypeptides derived from SEQ ID# 61 significantly improved the sensitivity of immunoassays, and that the amended claim 2 brings it into the scope of claim 1.

The arguments have been fully considered and found persuasive persuasive in part.

As discussed above, the amendments do not change the scope of the claim and the improvement or limitation that the polypeptide derived from SEQ ID #61 significantly improved the sensitivity of immunoassays is not what is claimed. Furthermore, the example cited, ^{in resp.} pages 54- 57, does not use SEQ ID#61 but uses composite clones, see page 35, lines 25- 30 and page 38, lines 5- 10. It is also noted by the Examiner that these clones do not meet the limitation of claim 1 because if the whole fusion peptide is considered, then the polypeptide is less than 80% identical to SEQ ID#61 or if only the HIV O env portions are considered, then the portion is only 50% or less the length of SEQ ID#61 and could never be 80% identical because even though it has 100% local identity to SEQ ID#61, it could only be as identical as the percent length it shares.

NEW REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how 80% identical used in claim 1 is defined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by EMBL and NCBI ACESSION NUMBER X96526.

On reconsideration, the rejection of claims 1 and 2 under 103(a) is withdrawn, because the printed publication does not enable an isolated protein with at least 80% identity to SEQ ID# 61. The sequence database, however, does describe and enable an isolated protein meeting the claim limitations. The 1.131 declaration of Sushil Devare has been considered, but is not effective in overcoming this rejection, for

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several reasons. First, since the declaration is not signed by all the inventors, it does not establish possession of the invention by "the inventor", because "the inventor" is an entity of JOHN R HACKETT, JR, JULIE YAMAGUCHI, ALAN M. OLDEN, CATHERINE A. RENNAN, ROBERT K. HICKMAN, and , SUSHIL G. DEVARE. Second, the declaration shows reduction to practice of one species within the claimed genus. This species is different from the species disclosed by the reference. The fact pattern is different from *In re Stempel* (241 F.2d.755, 113 USPQ 77, 1957). In *Stempel* it was held that "all the applicant can be required to show is priority with respect to so much of the invention as the reference happens to show. When he has done that he has disposed of the reference." Here, applicant is showing priority with respect to something different from what the reference shows. In other words, the claim is drawn to a genus, the reference is drawn to a species, and the declaration shows priority for a different species. Since the species is different from the reference, and since the declaration does not show possession of the genus before the reference date, the declaration is not effective to establish priority of invention for the generic claims.

Conclusion

No claim is allowed. Because this is an RCE, this office action is made non-final, even though there are rejections that are maintained from the previous office action and there are new rejections based on the amendment.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
November 26, 2002


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800 160